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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/825,105	04/03/2001	Michael W. Russell	D6321	3233

7590 08/26/2003

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EXAMINER
LI, QIAN J

ART UNIT	PAPER NUMBER
1632	11

DATE MAILED: 08/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action	Application No. 09/825,105	Applicant(s) RUSSELL ET AL.	
	Examiner Q. Janice Li	Art Unit 1632	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 26 July 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.

b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2. ☐ The proposed amendment(s) will not be entered because:

   (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);

   (b) ☐ they raise the issue of new matter (see Note below);

   (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

   (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____.

3. ☐ Applicant's reply has overcome the following rejection(s): _____.

4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5. ☒ The a)☐ affidavit, b)☐ exhibit, or c)☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: *See Continuation Sheet*.

6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7. ☒ For purposes of Appeal, the proposed amendment(s) a)☐ will not be entered or b)☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

   The status of the claim(s) is (or will be) as follows:

   Claim(s) allowed: _____.

   Claim(s) objected to: _____.

   Claim(s) rejected: *1-3,6 and 24-29*.

   Claim(s) withdrawn from consideration: _____.

8. ☐ The proposed drawing correction filed on _____ is a)☐ approved or b)☐ disapproved by the Examiner.

9. ☐ Note the attached Information Disclosure Statement(s)(PTO-1449) Paper No(s). _____.

10. ☐ Other: _____

ANNE M. WEHBE' PH.D
PRIMARY EXAMINER

Continuation of 5. does NOT place the application in condition for allowance because:

Claims 1-3, 6, and 24-29 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Toida et al (Infect Immunity 1997;65:909-15) in view of Rappuoli et al (Immunol Today 1999 Nov;20:493-500), and further in view of Schodel et al (Infect Immunity 1989;57:1347-50; and Vaccine 1990;8:569-72) and Connell et al (Immunol Lett 1998;62:117-20; and Infect Immunity 1992;60:1653-61).

In paper No. 10, Applicants again argue the references separately, attacking Toida et al, Rappuoli et al, Schodel et al, and Connell et al references individually, this is improper as indicated in the Office action paper#9, pages 3-5.

Additionally, applicants argue that the structural differences between type I and type II heat labile enterotoxins are significant, they will no cross-react with each other, one would expect the functional differences. Similar arguments have been addressed in the Office action paper#9, page 4, citing the teaching of Connell et al, which acknowledges the significant structural differences in the B subunit of LT-I and LT-II, and at the same time, indicating that the two share similar functions, and only differ in the efficiency.

Further, Applicants cited table 2 of Connell 1992 reference, indicating that certain heterologous hybrids of type I and II subunits have caused significant reduction in or even lost of the biological activates compared to the wild-type hybrids. The argument is not persuasive because instant claims are not drawn to using heterologous subunit hybrids of LT-I and LT-II, thus, the biological activities of the recited heterologous hybrids are irrelevant to the standing rejection. The claims are drawn to using homologous type II heat-labile enterotoxin, and the Connell references are relied upon as a showing that the structural difference of the B subunit does little toward the adjuvanticity of LT-II and LT-I.

With respect to In re Kerkhoven, 205 USPQ 1069 (CCPA 1980), applicants argue that the prior art has clearly taught significant structural differences between type I and type II enterotoxins, but does not teach the two would have the same or similar immunostimulatory functions in spite of their difference. The arguments are not persuasive because, as indicated in the previous Office action, Connell 1998 reference clear states that LT-IIa exhibits an adjuvant activity that is equal to that of cholera toxin (abstract), and Connell 1992 reference clearly teach LT-IIa, LT-IIb, and LT-I possess similar biological activities (first three rows of table 2).

Therefore, for reasons of record and set forth above, the rejection stands.

Claims 1-3, 6, and 24-29 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Russell et al (US 6,030, 624), in view of Rappuoli et al (Immunol Today 1999 Nov;20:493-500), and further in view of Schodel et al (Infect Immunity 1989;57:1347-50; and Vaccin 1990;8:569-72) and Connell et al (Immunol Lett 1998;62:117-20; and Infect Immunity 1992;60:1653-61).

In addition to presenting similar argument as above, applicants also argue that even though one skilled in the art might find it obvious to try various combinations of the elements culled from these references, "obvious to try" is not the standard under 35 U.S.C. 103(a). In response, the Office has not only presented the motivation to try but also presented evidence that the success is reasonably expected as taught by Connell et al and Rappuoli et al, which meet the standard under 35 U.S.C. 103(a) because MPEP (2143.02) states, "Obviousness requires only a reasonable expectation of success"

Therefore, for reasons of record and set forth above, the rejection stands.